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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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[REDACTED] EXAMINER

LOEB, BRONWEN

[REDACTED] ART UNIT [REDACTED] PAPER NUMBER

1636

DATE MAILED: 02/24/2003

37

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 09/029,579 | LANDEGREN, ULF | |
| | Examiner | Art Unit | |
| | Bronwen M. Loeb | 1636 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 15 Oct. 2002 and 10 Dec. 2002.

2a) This action is FINAL. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 7 and 9-12 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 7 and 9-12 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some * c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

| | |
|--|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ . | 6) <input type="checkbox"/> Other: _____ . |

DETAILED ACTION

This action is in response to the amendment filed 15 October 2002 and the sequence response filed 10 December 2002. The 15 October 2002 amendment amended claims 7, 9, 11 and 12 and cancelled claim 8. The 10 December 2002 amendment provided a substitute computer readable format of the sequence listing.

Claims 7 and 9-12 are pending.

Sequence Compliance

1. The computer readable format filed 10 December 2002 has been entered in the case. The application is now in sequence compliance.

Response to Amendment

2. Claims 7 and 9-12 stand rejected under 35 USC §102(b) as being anticipated by Nilsson et al (Science (1994) 265:2085-2088) for reasons of record and as further discussed below.

Claims 11 and 12 stand rejected under 35 USC §112, first paragraph for insufficient written description for reasons of record and as further discussed below.

Claims 11 and 12 stand rejected under 35 USC §112, second paragraph, as being indefinite for reasons of record and as further discussed below.

3. New rejections, necessitated by Applicant's amendment, are set forth below.

Response to Arguments

4. With respect to the rejection of claims 7 and 9-12 under 35 USC §102(b) as being anticipated by Nilsson et al, Applicant's arguments have been fully considered but are deemed not persuasive.

Applicant argues that amended claim 7 now recites a padlock probe composition comprising a pharmaceutically acceptable carrier and that Nilsson et al "neither teaches nor discloses" this composition. This is not persuasive. With regard to "pharmaceutically acceptable carriers", the specification teaches only that they are known in the art. The ligation buffer (10 mM Tris, pH 7.5, 10 mM magnesium acetate, 50 mM potassium acetate and 10 mM ATP) disclosed in the figure legend to Fig. 4 of Nilsson et al is comprised of components considered to be pharmaceutically acceptable. Rajagopalan et al (USP 5,162,109) teaches tris as a pharmaceutically acceptable carrier (col. 7, lines 56-68). Shelley et al (USP 5,505,961) teaches pharmaceutically acceptable carriers comprising potassium acetate (col. 2, lines 45-64). Mills (USP 5,132,118) teaches pharmaceutically acceptable carriers comprising potassium acetate and magnesium acetate (col. 7, lines 28-68). Rapaport (USP 5,227,371) teaches pharmaceutically acceptable carriers comprising adenosine triphosphate (ATP) (col. 5, lines 9-55). Since all of the components are considered pharmaceutically acceptable, absent evidence to the contrary, this buffer is considered to be a pharmaceutically acceptable carrier. Thus, Nilsson et al anticipates the amended claims.

The rejection is maintained.

5. With regard to the rejection of claims 11 and 12 under 35 USC §112, second paragraph as being indefinite, Applicant's arguments have been fully considered but are deemed not persuasive.

Applicant argues that chemical compounds and functional groups which are capable of joining the end part of oligonucleotides are well recognized in the art. While this may be true, the specification does not teach that this is the definition of the phrase "mutually chemically reactive compound". Furthermore this is not a term of art. A search of three databases of non-patent literature (MEDLINE, BIOSIS and EMBASE) and a patent database (CAPLUS) gave a single "hit" on this term: a Japanese patent, JP 50054409. A single reference using this phrase cannot be said to support that a phrase is a term of art. As set forth in the rejection in the previous action, the meaning of this term is unclear. Applicant has not explicitly addressed this issue. The rejection is maintained.

6. With regard to the rejection of claims 11 and 12 under 35 USC §112, first paragraph for insufficient written description, Applicant's arguments have been fully considered but are deemed not persuasive.

Applicant argues that chemical compounds and functional groups which are capable of joining the ends of oligonucleotides are well recognized in the art and cites a reference which teaches oligonucleotides having thiophosphoryl and bromoacetamido groups on their ends. The reference was not provided. As discussed above, "mutually chemically reactive compound" is not a term of art and is not defined in the

specification. Thus, it is unknown whether the cited reference is relevant to this phrase or not. The rejection is maintained.

New Grounds of Rejection

Claim Rejections - 35 USC § 112

7. Claim 12 is rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 12 is vague and indefinite in reciting dependency on itself. As a result, the metes and bounds of the claim cannot be ascertained.

Conclusion

Claims 7 and 9-12 are rejected.

Certain papers related to this application may be submitted to Art Unit 1636 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). The official fax telephone numbers for the Group are (703) 308-4242 and (703) 305-3014. NOTE: If Applicant does submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bronwen M. Loeb whose telephone number is (703) 605-1197. The examiner can normally be reached on Monday through Friday, from 11:00 AM to 7:30 PM. A phone message left at this number will be responded to as soon as possible (usually no later than the next business day after receipt by the examiner).

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Remy Yucel, can be reached on (703) 305-1998.

The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Bronwen M. Loeb, Ph.D.
Patent Examiner
Art Unit 1636

February 13, 2003


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